ICH update

January 15th 2016
Chair, JPMA ICH Committee
VP, New Drug Regulatory Affairs Dep. DST
Hironobu Saito
ICH Structure

Member: JP: MHLW/PMDA+JPMA  Europe: EC/EMA+EFPIA  USA: FDA+PhRMA
Observer: Health Canada, EFTA(Switzerland), WHO
Secretariat: IFPMA

Steering Committee

EWG (Efficacy)
  Clinical Part

EWG (Safety)
  Animal Part

EWG (Quality)
  API and Drug formulation Part
  EWG (Multidisciplinary)

Informal WG

GCG
+RHI (APEC, ASEAN, African (EAC, SADC), Arabian (GCC), South America (PANDRH)
+Several DRA/DoH (Australia, Brazil, Singapore etc.)

2 times a year (F2F meeting)
2015 December : Jacksonville (US)
2015 June : Fukuoka (Japan)
2014 November : Lisbon (Portugal)
ICH Process for new guideline

- **Consensus Building – Technical Document**
  - Step 1
- **Confirmation of six-party consensus on Technical Document**
  - Step 2a
- **Adoption of draft guideline by Regulator Parties**
  - Step 2b
- **Regulatory consultation and Discussion**
  - Step 3
- **Adoption of an ICH Harmonised Tripartite Guideline**
  - Step 4
- **Implementation**
  - Step 5
- **Publishing**
  - Public Comments
- Proposal from Regulator/Industry Concept Paper of each guideline
Enhancing the Steering Committee activities

• Activities of the ICH Steering Committee
  In addition to approval of the guidelines, 1) organizational restructuring, 2) newly projects, and 3) education support have been considered.

• Specific actions taken
  – Establishment of Assembly (facilitating participation of countries other than Japan, the United States and Europe)
  – Proposal of new guidelines
  – Acceleration of revision of guidelines
  – Promoting education to each country
ICH Organization (From 2015 December)

Assembly
Management Committee

EWG (Efficacy)

EWG (Safety)

EWG (Quality)

EWG (Multidisciplinary)

Informal WG

MHLW/PMDA+JPMA EC/EMA+EFPIA
FDA+PhRMA, Health Canada,
EFTA(Switzerland)

Observer (the future to be member)
1) RHI (APEC, ASEAN, African (EAC, SADC),
Arabian (GCC), South America (PANDRH)
2) DRA/DoH (Australia,
Brazil, China, Korea,
Russia, Singapore etc.)
3) International Associations
Generic, API, OTC, Bio
Sub-Committee Activity in Managing Committee

• Financial Sub-committee (cascade down)
• Membership Sub-committee
  – Evaluation process
• Communication Sub-committee
  – 2016 Communication strategy
  – Transparency strategy
• Training Sub-committee (New)
• New Topic Sub-group (New)